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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------------|
| 10/650,931 | 08/27/2003 | Jong-Soo Woo | DE-1500 | 8064 |
| 1109 7590 09/07/2007 ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK,, NY 10020-1182 | | | EXAMINER SPIVACK, PHYLLIS G | |
| | | | ART UNIT 1614 | PAPER NUMBER |
| | | | MAIL DATE 09/07/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/650,931

Applicant(s)

WOO ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 15 and 18, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6-15-07</u> . | 6) <input type="checkbox"/> Other: _____ |

An Amendment and a Declaration under 37 CFR §1.132 both filed June 15, 2007 are acknowledged. A Supplemental Amendment filed June 18, 2007 is further acknowledged that is drawn to the same declaration referenced *supra* but with the required signature. Claims 2-4 and 7 are canceled. Claims 1, 5, 6, 9 and 10 remain under consideration wherein the subject matter under consideration remains those sustained-release compositions for oral administration comprising the drug nifedipine, a mixture of sodium alginate and xanthan gum, representing the carrier for sustained release of nifedipine and a mixture of hydroxypropyl methylcellulose and propylene glycol alginate, representing the gel hydration accelerator.

Those compositions comprising other drugs, carriers and gel hydration accelerators remain withdrawn from consideration by the Examiner as drawn to non-elected inventions. Re-affirmation of the elections is again requested when Applicants respond to this Office Action.

An Information Disclosure Statement filed June 15, 2007 is further acknowledged. The three cited references on this IDS had previously been cited on the 892 form mailed with the first Office Action.

Applicants' arguments have been fully considered and are persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The Declaration presented by Jong-Soo Woo provides a showing of time-dependent changes in the release rate of nifedipine in a composition comprising a carrier of sodium alginate and xanthan gum and a gel hydration accelerator of hydroxypropyl methylcellulose and propylene glycol alginate, both in the claimed ratios.

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A zero order release pattern is noted. The following rejection constitutes the sole rejection applied to the present claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1, 5, 6, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In each of the claimed ratios of instant claims 1, 6 and 10, a range is recited via the symbol "~". This designation renders the claims indefinite because it indicates that the ranges are relative.

Accordingly, the metes and bounds of the claimed subject matter cannot be precisely determined.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 2, 2007


Phyllis Spivack
**PHYLLIS SPIVACK
PRIMARY EXAMINER**